JUL 2 1 2003

K031802

510K Summary

Date:	April 21, 2003
Applicant	Coramex S.A. Lauro Villar 94-B 02440 – Mexico, D.F. Mexico Registration Number: 9613804
Contact Person	Massimo Bachi - President
Telephone (Applicant)	011-52-55-5394-1192
Device Name:	Corix 70 Plus-USV
Common Name:	X-Ray
Classification Name:	Unit, X-Ray, Extraoral
Legally Marketed device to which firm is claiming equivalence:	Explor-X 70
Description of the Device:	Corix 70 Plus-USV is a Dental X-Ray generator; its primary use is for intra oral image receptor radiology. For such application, a peak voltage of 70 kV_p has been demonstrated to give a high quality film with a good film quality/risk ratio. This is also enhanced by the fact that the tube current has the value of 8 mA, assuring effectiveness. The soft X-Ray are filtered by the inherent filtration and by an additional filter to guarantee the minimum 2 mm eq. of Al required by specifications. Exposure times are microprocessor controlled, assuring a high constancy and also repeatability. The high voltage generator is enclosed in a cover. The beam-limiting device is formed by a circular cone with a maximum diameter of 60 mm. The weight of the tubehead is 7.5 kg. The certified components may be assembled in different configurations in terms of arms and mounting. The control box assembly and the timer are combined as one and include all the electronics to power the high voltage transformer contained on the tubehead. This power supply part is covered by a

	plastic prismatic cover. X-Ray exposures are signaled by both acoustic and optical signals. The operator may choose exposure times ranging from 0.03 up to 3.00 seconds.
Intended use of the device:	Corix 70 Plus-USV is an extra oral source X-ray system for dental radiographic examination and diagnosis of diseases of the teeth.

Summary of the Technological characteristics of Corix 70 Plus-USV compared to the predicate device Explor-X 70.

	Explor-X 70	Corix 70 Plus-USV
Intended Use	Extra oral source X-ray system for dental radiographic examination and diagnosis of diseases of the teeth	Extra oral source X-ray system for dental radiographic examination and diagnosis of diseases of the teeth
High Voltage value	70 kV_p	70 kV_p
Tube current	8 mA	8 mA
Tube insert	CEI OCX 70-G	CEI OX/ 70-P
H.V. type:	Single phase, self rectifying	Single phase, self rectifying
X-Ray exposure time control	Microprocessor Controlled	Microprocessor Controlled
Compensation of Line Voltage Fluctuations	Automatically by software	Automatically by software
Safety features	Dead man command Safety backup timer	Dead man command Safety backup timer Safety backup timer
Signaling devices	Acoustic and visual signal Optional remote signaling	Acoustic and visual signal Optional remote signaling

The main differences of the Corix 70 Plus-USV with respect to the SE device are mainly aesthetics. The functionality and technology are similar.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 21 2003

Coramex S.A.
% Mr. Al Sosa
Chicago X-Ray Systems, Imc.
251 E. Dundee Road, Suite # 6
WHEELING IL 60090

Re: K031802
Trade/Device Name: Corix 70 Plus-USV
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: 90 EHD
Dated: April 21, 2003
Received: June 13, 2003

Dear Mr. Sosa:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510 (k) NUMBER: K031802
DEVICE NAME: Corix 70 Plus-USV
INDICATIONS FOR USE:

The indication for use of the Corix 70 Plus-USV (with DPM timer) is **extra oral source X-ray system** for use in dentistry as required for the radiographic examination and diagnosis of the dental anatomy.

(PLEASE DO NOT WRITE BELOW-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ (Per 21 CFR 801.109) OR Over-The-Counter-Use _____ (Optional Formay 1-2-96)

David A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K031802

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